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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,192	06/20/2002	Kattesh V. Katti	0994.00133	6247

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EXAMINER

KRASS, FREDERICK F

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,192

Applicant(s)

KATTI ET AL.

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12-22-03</u> | 6) <input type="checkbox"/> Other: _____ |

Obviousness-Type Double Patenting Rejection

Claims 1-4 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,843,993, taken in view of Fricker ("Medicinal chemistry and pharmacology of gold compounds", *Transition Met. Chem.*, vol. 21, 377-383 (1996)).

This rejection is withdrawn in view of the terminal disclaimer filed by Applicant.

Scope of Enablement Rejection

Claims 5-7 were rejected under 35 U.S.C. 112, first paragraph, as being broader in scope than their enabling disclosure.

This rejection is maintained.

Applicant argues that the instantly claimed compounds have been tested in "numerous different types of cancer", and that "the fact that multiple, unrelated types of cancer have been treated successfully" is indicative of the ability of the claimed compounds to be utilized broadly for various forms of cancer. The examiner does agree that testing with three very specific types of cancer (prostate, colon and gastric) is representative of the many thousands of types of cancers which exist. Furthermore, Applicant's statements later in the response

(the full paragraph on page 5 therein) take the position, inconsistent with the argument made here, that treatment with gold compounds is extremely unpredictable. Moreover, the cited prior art recognizes the unpredictability of gold compounds in treating different cancer types: see for example Fricker at the last full paragraph of the lefthand column at page 379, where gold compounds having activity against an initial cancer type were found unsuccessful against other types when further tested.

Applicant argues that the present claims recite methods for preventing the spread of cancer, or for treating cancer, and thus should not be rejected since they do not recite "curing" cancer. This may be so, but it does not address the substance of the previous rejection. Inhibiting metastasis may not be a cure, but metastasis itself is still extremely unpredictable, as previously discussed. This is especially so since no particular tissue type is recited as being the source or target of the metastasis. The same applies for "arresting" cell growth (with no specific cell type being specified).

Obviousness Rejection

Claims 1-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Katti et al (USP 5,843,993) in view of Fricker ("Medicinal chemistry and pharmacology of gold compounds", *Transition Met. Chem.*, vol. 21, 377-383 (1996)).

This rejection is maintained.

Applicant argues that the primary reference contains "no disclosure or suggestion that the radiopharmaceutical could be anything other than radioactive". The examiner disputes this assertion; while the reference does not disclose non-radioactive gold specifically, it does not in any way state that the complexes disclosed therein must be radiopharmaceuticals or could not be non-radioactive. Instead, the prior art states at col. 1, lines 14 and 15 that "pharmaceutical, especially radiopharmaceuticals" may be used, which appears to be an expansive, not restrictive, suggestion of the types of compounds which may be used.

Applicant further argues that the secondary reference provides "no indication" that non-radioactive gold can effectively be used in treating cancer. Applicant goes on to state that compounds "have been used containing non-radioactive gold in attempting to treat cancer, however the toxicity reports from these studies have indicated that gold is not effective in treating cancer and instead is toxic". The examiner can find no support in the record for these assertions. To the contrary, Fricker et al disclose that various gold compounds have demonstrated antitumor activity in established laboratory models against leukemia and melanoma, at the very least. That disclosure does not provide any expectation of undue toxicity in treatment; moreover, even if it did, that would not "teach away" from therapeutic use – most chemotherapeutics now in use are in fact very toxic, having many adverse side effects.

Applicant also argues that there is "no clinical analysis that forms a linkage between the treatment of arthritis and the treatment of cancer". Accordingly,

"there is no indication, and in fact there is a teaching away from utilizing gold in treating cancer". This line of argument is not understood. First, even if applicable, this would involve instant claim 5 only (drawn to methods of treating cancer). No "linkage" is needed to use the secondary reference teachings concerning anticancer activity; the reference clearly discloses the treatment of arthritis and cancer as alternative and unrelated therapies. (Hence their discussion under separate subsections on pages 378 and 379 of the secondary reference). And claims 1-4 are drawn to the complexes themselves, regardless of the disease being treated, so they would be rendered obvious by the treatment of arthritis, even were cancer treatment not disclosed.

Action is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;
Tuesday: 10-6:30PM;
Wednesday: off;
Thursday: 10-6:30PM; and
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Marianne, can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Frederick Krass', written in a cursive style.